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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,710	05/16/2001	Franciscus Bernardus Gemma Benneker	POT-010US3	9651

34610 7590 09/16/2003

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: ~~1025~~

This is in response to applicant's request filed on May 27, 2003. The rejections have been maintained. A copy of the Attachment to the advisory with Director's approval is attached herewith.

Art Unit: 1625

--ATTACHMENT TO ADVISORY--

The final rejection of Paper No.10 is maintained for reason of record because applicants have provided no factual evidence to obviate the rejections. The arguments are not persuasive and no good reason why they could not be presented earlier since no new ground of rejection was made in the final. The rejections of record can be found in Paper no. 10 as summarized as following:

The rejection of claims 27-29 under 35USC 102(b) is maintained:

Applicants argument with respect to Craig et al. '927 is irrelevant since each application should be evaluated on its own merit. When an allowable claim is found, then, an assessment of whether two parties are claiming the "same" invention to warrant declaration of interference.

In the instant case, it is noted that while the broad claims 27-29 are anticipated by prior art Barnes '723 or Ward et al. '132, there is insufficient evidence to warrant "identical products" of the instant claims with the products of Craig et al. '927. It is well recognized that anhydrous, hemihydrates or solvates of paroxetine salt are different products (see Ward '132 columns 4-5). The product that will be obtained will be affected by the particular choice of solvents in crystal formation. While species anticipating the claims rendered the claims rejectable, the specific solvents of the dependent claims employing ethylacetate evidenced that the product by process of the instant claims will be a paroxetine hydrochloride anhydrate with 0.4% ethylacetate (see example 12 Ward '132), thus, are patentably distinct from the hemihydrate exemplified by Craig et al. '927 (see examples 51-53).

The rejection of claims 24-25 under 35 USC 103(a) over Stemp et al. '496 in view of Barnes et al. '723 is maintained for reason of record.

Applicants argued that conversion of paroxetine methanesulfonate to hydrochloride can produce high purity is not expected by Stemp et al. '496 is not persuasive. Initially, it is noted that "purity" of product is not a limitation of the claims. Further, it was clearly delineated that in

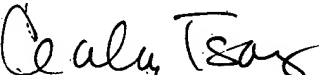
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establishing a *prima facie* case that (I) the various pharmaceutical salt, (ii) the explicit exemplification together with conventional teaching of multiple examples i.e. Barnes '723, and (iii) the reasonable expectation, i.e. the examples recited in the prior art all evidenced that such process operates in analogous manner, thus, the know how, motivation, and reasonable expectation of success are found in the prior art. The elucidation that the product being made would commend high purity is hindsight, i.e. after one skilled in the art adopted the *prima facie* obvious process to obtain the product.


The high purity product has of the issued patent was produced by the process of claim 26 which has been objected to but would be allowable. Applicants have not presented an independent claim commensurate to the subject matter of claim 26.

WP/Chang
Sept. 4, 2003

Celia Chang
Primary Examiner
Art Unit 1625


Cecilia Tsang, SPRE 1600

Approval


Bruce M. Kisliuk
Director, Group 1600